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| Filing Date | September 27, 2000 |
| First Named Inventor | Bruce W. GIBBS |
| Art Unit | 3762 |
| Examiner Name | Patricia BIANCO |
| Attorney Docket Number | BC-0256-P02 |

ENCLOSURES (Check all that apply)

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| | | | |
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| Firm Name | Gambro, Inc. | | |
| Signature | <i>Laura M. Butterfield</i> | | |
| Printed name | Laura M. Butterfield | | |
| Date | 12-20-2004 | Reg. No. | 47466 |

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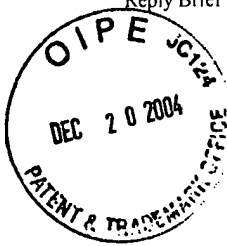
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appl. No. : 09/672519
Applicant : Bruce W. GIBBS
Filed : 09/27/2000
TC/A.U. : 3762
Examiner : Patricia BIANCO
Docket No. : BC-0256-P02
Customer No. : 24994

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APPEAL BRIEF UNDER 37 C.F.R §1.192

Pursuant to 37 C.F.R §1.192, Appellants submit this Appeal Brief, in triplicate, to the Board of Patent Appeals and Interferences, from the July 26, 2004 final Office Action. In light of the Notice of Appeal filed on October 21, 2004, this Appeal Brief is being timely filed along with payment of the Appeal Brief fee.

I. Real Party in Interest

The real party in interest is Gambro, Inc., the assignee of the entire right, title and interest in the application at issue.

II. Related Appeals and Interferences

There are currently no related appeals or interferences pending before the Board of Patent Appeals and Interferences.

III. Status of Claims

Claims 1-6 are involved in this appeal and are set forth in the attached Appendix. In her Advisory Action the Examiner stated that claims 1-10 stand rejected for purposes of appeal, however, claims 7-11 were canceled by Applicants in the Amendment and Response After Final filed on August 12, 2004. The Examiner entered the claim amendments as noted in the Advisory Action dated September 20, 2004. Therefore, claims 1-6 are the subject of this appeal.

IV. Status of Amendments

As set forth above, claims 7-11 were canceled by Applicants in the Amendment and Response After Final filed on August 12, 2004. The Examiner entered the claim amendments/cancellations in the Advisory Action dated September 20, 2004.

V. Summary of Invention

The present invention generally relates to an apparatus for use in blood separation. Although such an apparatus has applicability in various fields to separate many different substances, one exemplary use relates to a leukoreduction filter preconnected to an apheresis disposable for filtering the collected blood component. In conjunction with this aspect, the instant invention provides a preconnected disposable comprising a blood removal and return assembly, a separation or blood processing vessel for separating blood into components, a cassette assembly with internal passageways and a red blood cell collection assembly, which comprises a red blood cell collection bag connected to a leukoreduction filter which is connected to a red blood cell storage bag (see claim 1.)

Figs. 1 and 2A-2C show exemplary aspects of the invention. As illustrated in Figs. 2A-2C, blood-primable preconnected extracorporeal tubing circuit 10 comprises a cassette assembly 110 and a number of tubing assemblies 20, 50, 60, 80, 90, 100 interconnected therewith. Generally, blood removal/return tubing assembly 20 provides a single needle interface between a donor/patient 4 and cassette assembly 110, and blood inlet/blood component tubing subassembly 60 provides the interface between cassette

assembly 110 and blood processing vessel 352. An anticoagulant tubing assembly 50, platelet collection tubing assembly 80, plasma collection tubing assembly 90, red blood cell collection assembly 950 and vent bag tubing subassembly 100 are also interconnected with cassette assembly 110. (See page 11 of the specification.)

The RBC/plasma outlet tubing 64 of the blood inlet/blood component tubing assembly 60 is interconnected with integral RBC/plasma passageway 170 of cassette assembly 110 (see Fig. 2B). The integral RBC/plasma passageway 170 includes first and second spurs 170a and 170b, respectively. The first spur 170a is interconnected with RBC/plasma return tubing loop 172 to return separated RBC/plasma to a donor/patient 4. For such purpose, the RBC/plasma return tubing loop 172 is interconnected to the top of blood return reservoir 150 of the cassette assembly 110. The second spur 170b may be closed off, or may be connected with an RBC/plasma collection tubing assembly 950 (see Figs. 2A and 2C) for collecting RBC/plasma during use. RBC collection tubing assembly 950 includes RBC collector tubing 952, an RBC collection reservoir or bag 954, an RBC filter/storage sub-assembly including an RBC storage reservoir or bag 958, an RBC leukoreduction filter 960 and an air removal bag 962. A sterile barrier filter/drip spike assembly 956 may also be included and attached to RBC bag 954 through an optional frangible connector 968. Bags 954 and 958 are connected to each other by two tubings 964, 965 between and to each of which the RBC leukoreduction filter 960 is connected. Collection bag 954 is interconnected to RBC filter 960 through frangible connector 967. The air removal bag 962 is attached to the RBC storage bag 958 by a tubing 966. The RBC collection tubing sub-assembly is a preconnected part of the disposable. (See page 15.)

Following the collection of the desired quantity of red blood cells, a storage solution may be added to the red blood cell reservoir or bag 954 preferably through the opening of optional frangible connector 968. (See pages 74-75.)

The storage solution may be contained in a separate storage solution bag that can be selectively interconnected to the RBC collection bag 954. Such selective

interconnection may be provided via sterile-docking to tubing 955 as an example (see Figs. 2A and 2C) utilizing a sterile connecting device.

After the storage solution has been added to the collected red blood cells in RBC reservoir 954, selective filtering may be desired to remove white blood cells. The red cell filter/bag assembly is preferably preconnected onto the disposable as shown in Figs. 1, 2A and 2C. The red cell filter/bag assembly preferably is preconnected to the collection bag 954 through tubing 964 containing frangible connector 967. (See page 76.)

Claim 1 is the sole independent claim involved in this appeal. As discussed in more detail below, claim 1 recites a preconnected disposable for an apheresis system comprising a blood removal and return assembly, a separation vessel for separating blood into components, a fluid flow cassette with internal passageways and a red blood cell collection assembly, which comprises a red blood cell collection bag connected to a leukoreduction filter which is connected to a red blood cell storage bag.

As explained below, the subject matter of this claim is not anticipated by Keller.

VI. Issues

A. Whether the rejection of claims 1, 5-6 under 35 USC 102(e) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

B. Whether the rejection of claim 2 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

C. Whether the rejection of claims 3 and 4 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) in view of US Patent No. 5,009,654 to Minshall (Minshall) should be reversed.

VII. Grouping Of Claims

All of the rejected claims do not stand or fall together.

Regarding the Section 102(e) rejection based upon Keller, claims 1, 5-6 stand or fall together.

Regarding the Section 103(a) rejection based upon Keller, claim 2 stands or falls on its own.

Regarding the Section 103(a) rejection based upon Keller in view of Minshall, claim 3 stands or falls on its own.

Regarding the Section 103(a) rejection based upon Keller in view of Minshall, claim 4 stands or falls on its own.

VIII. Argument

A. The rejection of claim 1, 5-6 under 35 USC 102(e) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

Claims 1, 5-6 should stand or fall together. Claims 1, 5 and 6 claim preconnected collection bags which are interconnected to a cassette assembly for receiving separated blood components from an apheresis system. The Keller reference does disclose collection bags for receiving separated blood components which are attached to a cassette assembly, however, as discussed below, the Keller reference does not disclose a disposable having a preconnected red blood cell filter.

In the final Office Action (and subsequent Advisory Action), the Examiner maintained her rejection of claims 1, 5-6 under 35 USC 102(e) based on Keller. In the Advisory Action, Examiner Bianco stated that "Keller's teaching is inherent that the filter would be interconnected or preconnected into the apparatus."

Applicants submit that the rejection of claims 1, 5-6 based on Keller should be reversed. As set forth in MPEP 2131 "A claim is anticipated only if each and every

element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.”

The Keller reference does not expressly disclose that the leukoreduction filter is interconnected or preconnected between the red blood cell collection bag and the red blood cell storage bag, as claimed in Applicants claim 1. As defined in Webster's Third New International Dictionary, *connected* is defined as "joined or linked together" and *pre* is defined as "earlier than: prior to: before." Nowhere in Keller is this preconnection before use disclosed.

The Keller reference also does not inherently disclose that the leukoreduction filter is preconnected between the red blood cell collection bag and the red cell storage bag.

As stated in *Motorola, Inc. v. Interdigital Technology Corp.* (930 F.Supp 952, 970 (D. Del. 1996), *aff'd in part and rev'd in part*, 121 F.3d 1461, 43 USPQ2d 1481 (Fed. Cir. 1997)) “[A]n important part of any inherency analysis is whether the missing element must necessarily be understood to be part of the reference. Mere possibilities or even probabilities are not enough to support a finding of anticipation.”

As taught in the Keller reference on column 55, beginning on line 21, if leukoreduction of the collected red blood cells is deemed appropriate, the red blood cell/storage solution mix can be connected to a commercially available red cell/filter bag so that red blood cells are gravity transferred from the collection bag through a filter and into a new storage bag. The mere possibility that a leukoreduction filter “can be connected” does not inherently imply that the filter is preconnected or integrated into the disposable set as claimed in the invention at issue.

As set forth in *Ex Parte Levy* (17 USPQ2d 1461,1464 (1990)), “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”

Again, as stated on column 55, line 30-35, “If (emphasis added) such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be (emphasis added) connected to a commercially available red cell filter/bag ...” The phrase “can be connected” implies that a positive connection step of a commercially available red cell filter is required should leukoreduction be deemed appropriate. Such teaching does not reasonably support the Examiner’s assertion that the prior art inherently discloses a preconnected leukoreduction filter. The word “if” is defined in Random House Webster’s Unabridged Dictionary as “a supposition, uncertain possibility.” According to Keller, if leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be connected to a red cell filter/bag. Therefore, according to the teaching of Keller, if leukoreduction is desired, a leukoreduction filter may or may not be used. It does not necessarily flow from this teaching that there is an interconnected or preconnected filter as an integral part of the disposable. A filter such as Applicants which is preconnected does not require any additional affirmative connection step.

Furthermore, because the leukoreduction filter of the present invention is preconnected into the disposable set, it provides additional advantages over the Keller reference. Before this invention, leukoreduction filters were sterile docked manually to both a red blood cell collection bag and a leukoreduced red blood cell storage bag after the collection bag was disconnected from the rest of the disposable set. Having a leukoreduction filter preconnected to a disposable set prevents the additional steps of sterile docking/connecting the leukoreduction filter to the bag containing collected red blood cells to be leukoreduced and the storage bag.

Additionally, having the filter preconnected to the disposable prevents problems with maintaining the sterility of the disposable. Because the filter is preconnected in the disposable, no additional connection steps are required. This lack of connection steps prevent the possibility that the disposable might be contaminated by an operator inadvertently touching the filter or tubing while manually connecting the filter to the red blood cell collection bag and storage bag.

B. The rejection of claim 2 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) should be reversed.

Claim 2 should stand or fall on its own. Claim 2 claims an air removal bag interconnected to the red blood cell storage bag for receiving air from the red blood cell storage bag. As discussed below, Keller does not teach the feature of preconnecting a bag to collect air which has been removed from a red blood cell storage bag.

Applicants submit this rejection should be reversed.

Applicants disagree with the Examiner's assessment that "it would have been obvious at the time of the invention to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in the art." As set forth in MPEP 2144.04 VI. C. "The mere fact that a worker in the art could rearrange the parts in the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of the appellant's specification, to make the necessary changes in the reference device." Ex parte Chicago Rawhide Mfg. Co. 223 USPQ 351, 353.

There is no teaching or suggestion in the Keller reference which would enable one skilled in the art to interconnect an air removal bag to a red blood cell storage bag as claimed in Applicant's claim 2. As taught on column 19, beginning on line 23, the vent

bag 104 of Keller is interconnected via vent bag tubing assembly 100 to the top of the blood return reservoir 150 of the cassette assembly 100. During use, air is removed which was present since packaging within the cassette assembly.

The blood return reservoir located in the cassette assembly of Keller does not store red blood cells which have been leukoreduced. There is no suggestion in Keller that this reservoir could contain leukoreduced red blood cells. Therefore, it is not a mere rearrangement of parts as the Examiner suggests. It would not be obvious for one skilled in the art to attach an air removal bag to a separate and distinct bag which is used to store leukoreduced red blood cells.

C. The rejection of claims 3 and 4 under 35 USC 103(a) based on US Patent No. 6,200,287 to Keller (Keller) in view of US Patent No. 5,009,654 to Minshall (Minshall) should be reversed.

Claim 3 should stand or fall on its own. Claim 3 claims a preconnected disposable having a frangible connector located in the tubing between the leukoreduction filter and the red blood cell collection bag. Minshall does not disclose use of a frangible connector to enable red blood cells to pass through the tubing between a filter and a red blood cell collection bag.

Claim 4 should stand or fall on its own. Claim 4 claims a preconnected disposable having a frangible connected located in the tubing between the red blood cell collection bag and a storage solution container. Minshall does disclose a connection between a storage solution bag and a liquid administration and processing apparatus, however the connectors are not frangible connectors. The connectors are flexible plastic sleeves which join two separate tubing pieces together. The tubing of Applicants invention is a single distinct piece of tubing which contains the frangible connector.

Applicants submit this rejection should be reversed because the Office Action fails to set forth a *prima facie* showing of obviousness.

As set forth in MPEP §2243, to establish a *prima facie* case of obviousness, three basic criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references must teach or suggest all of the claimed elements and limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner's rejection does not meet the obviousness test set forth above. As previously discussed above, the Keller reference does not disclose a preconnected disposable with a leukoreduction filter interconnected to a red blood cell collection bag and a red blood cell storage bag. The Minshall reference does not disclose a single tubing with a frangible connector interconnected between a leukoreduction filter and a red blood cell collection bag (claim 3). Minshall discloses a tubing connector which is a flexible plastic sleeve which joins two separate and distinct tubing pieces together. Minshall also does not disclose a second single tubing with a frangible connector interconnected between a red blood cell collection bag and a storage solution container (claim 4). There is no teaching or suggestion in either reference to combine them. Furthermore, if combined, the combination of these references would not produce the invention as claimed by Applicants.

IX. Conclusion

For at least the reasons given above, the Board of Patent Appeals and Interferences should reverse the claim rejection under 35 USC §102(e) and 103(a) and permit allowance of claims 1-6.

To the extent any extension of time under 37 C.F.R. §1.136 is required to obtain entry of this Appeal Brief, such an extension is hereby respectfully requested.

It is believed there is a fee of \$500.00 due for the filing of a brief in support of an appeal. Please charge this fee and/or any other fees due which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. §1.136, to our Deposit Account 32316.

Respectfully submitted,

12-20-2004
Date

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APPENDIX

Appealed claims:

1. (Original) A preconnected disposable for an apheresis system for separating blood into at least one component for collection, said disposable comprising

a blood removal/return assembly for removing blood and returning any uncollected components to the donor;

a cassette assembly interconnected to said blood removal/return assembly, said cassette assembly comprises integral fluid passageways for the passage of blood and blood components;

a blood processing vessel interconnected to said cassette assembly for separating blood received from the donor into components; and

a red blood cell collection assembly comprising

a red blood cell collection bag interconnected to said cassette assembly for receiving separated red blood cells when red blood cells are the component to be collected;

a leukoreduction filter interconnected to said red blood cell collection bag;

and

a red blood cell storage bag interconnected to said leukoreduction filter.

2. (Original) The preconnected disposable of claim 1 further comprising

an air removal bag interconnected to said red blood cell storage bag for receiving air from said red blood cell storage bag.

3. (Original) The preconnected disposable of claim 1 further comprising

first tubing interconnected between said leukoreduction filter and said red blood cell collection bag; and

a frangible connector in said first tubing for allowing said first tubing to be opened for the passage of red blood cells through said first tubing.

4. (Original) The preconnected disposable of claim 3 further comprising a second tubing interconnected to said red blood cell collection bag, said second tubing being selectively connectable to a storage solution container; and

a frangible connector in said second tubing for allowing said second tubing to be opened for the passage of storage solution therethrough.

5. (Original) The preconnected disposable of claim 1 comprising

a platelet collection bag interconnected to said cassette assembly for receiving separated platelets when platelets are to be collected.

6. (Original) The preconnected disposable of claim 1 comprising

a plasma collection bag interconnected to said cassette assembly when plasma is to be collected.